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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,603	10/30/2001	Alexander Gaiger	210121.465C6	3627
500	7590	12/14/2005	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 6300 SEATTLE, WA 98104-7092			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,603

Applicant(s)

GAIGER ET AL.

Examiner

Ron Schwadron, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 2,7,11,18-34 are drawn to peptides and compositions containing said peptide, classified in Class 514, subclass 2 and Class 530, subclass 323.
- II. Claims 1,3,4,8,11,15 are drawn to polynucleotides, classified in Class 514, subclass 44.
- III. Claims 5,16,11 are drawn to antibodies and compositions, classified in Class 424, subclass 130.1 and class 530, subclass 388.85.
- IV. Claims 10,11 are drawn to T cells, classified in Class 424, subclass 93.71.
- V. Claim 11 is drawn to APC, classified in Class 424, subclass 93.7.
- VI. Claims 12,13,17 are drawn to methods of treatment using peptides, classified in Class 514, subclass 885.
- VII. Claims 12,13,17 are drawn to methods of treatment using polynucleotides, classified in Class 514, subclass 43.
- VIII. Claims 12,13 are drawn to method of treatment using antibodies, classified in Class 424, subclass 138.1.
- IX. Claims 12,13,17 are drawn to method of treatment using T cells, Class 424, subclass 534.
- X. Claims 12,13,17 are drawn to methods of treatment using APCs, classified in Class 424, subclass 529.
- XI. Claim 9 is drawn to a method of expanding T cells using a peptide, classified in Class 435, subclass 2.
- XII. Claim 9 is drawn to a method of expanding T cells using nucleic acids, classified in Class 435, subclass 375.
- XIII. Claim 6 is drawn to methods of detection using polypeptides, classified in Class 435, subclass 7.2.
- XIV. Claim 14 is drawn to methods of detection using polynucleotides, classified in Class 435, subclass 6.
- XV. Claim 9 is drawn to a method of expanding T cells using APCs, classified in Class 424, subclass 373.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-V are different products. Invention I is drawn to peptides, while invention II is drawn to polynucleotides, while invention III is drawn to antibodies, while invention IV is drawn to T cells, and invention V is drawn to APC. These products are structurally different and have different art recognized uses. Inventions I-III are drawn to inanimate molecules while inventions V and IV are drawn to cells. Inventions V and IV differ in that the art recognizes that APC and T cells are two different and unique types of cells that are structurally and functionally not related. The products of inventions I-III are recognized in the art as structurally and functionally distinct with different art recognized uses. Therefore they are novel and unobvious in view of each other and are patentably distinct.

4. Inventions I and VI/IX/XIII_A are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as an immunogen for the production of antibodies which bind said peptide.

5. Inventions II and VII/XIV/XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as recombinant method for making the peptide encoded by said nucleic acid.

6. Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as immunopurification of the peptide which said antibody binds.

7. Inventions IV and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as immunogen for the production of antibodies which bind said T cell.

8. Inventions V and X/XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as immunogen for the production of antibodies which bind said APC.

9. Inventions VI to XV are different methods that use different ingredients to achieve different goals. The inventions are drawn to methods of detection versus methods of treatment versus a method of expanding T cells wherein the aforementioned methods use different ingredients to achieve different goals. The various methods of treatment use different products that are structurally and functionally distinct. The various methods of detection use different products that are structurally and functionally distinct. Therefore they are novel and unobvious in view of each other and are patentably distinct.

10. Inventions IV and XI/XII/XV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed cells could be made by expanding cells with patient cells that expressed the pertinent antigen.

11. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-XV is not required for any other group from Groups I-XV and Groups I-XV have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. The following species requirement is required if applicant elects a group that recites a specific peptide with a specific SEQ. ID.

This application contains claims directed to the following patentably distinct species of the claimed invention which are the specific peptides recited in claim which recite such peptides. These peptides are different peptides with different amino acid sequences.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

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and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644


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